510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:

K052876

B. Purpose for Submission:

Introduction of the antibiotic Telithromycin 15 µg BBL™ Sensi-Disc™

C. Measurand:

Telithromycin 15 µg

D. Type of Test:

Semi-quantitative Antimicrobial Susceptibility Test Disc

E. Applicant:

Becton Dickinson and Company, BD Diagnostic Systems

F. Proprietary and Established Names:

Telithromycin 15 µg BBL™ Sensi-Disc™

G. Regulatory Information:

1. Regulation section:

   866.1620 Antimicrobial Susceptibility Test Disc

2. Classification:

   II

3. Product code:

   JTN – Susceptibility Test Disc, Antimicrobial

4. Panel:

   83 Microbiology

H. Intended Use:

1. Intended use(s):

   Telithromycin 15 µg BBL™ Sensi-Disc™ are intended for use for semi-quantitative *in vitro* susceptibility testing by the agar disc diffusion test procedure of common rapidly growing and certain fastidious bacterial pathogens. These include the *Enterobacteriaceae, Staphylococcus* spp., *Pseudomonas* spp., *Acinetobacter* spp., *Enterococcus* spp., *Vibrio cholerae* and by modified procedures, *Haemophilus influenzae*, *Neisseria gonorrhoeae, Streptococcus pneumoniae*, and other streptococci.

2. Indication(s) for use:

   Telithromycin 15 µg BBL™ Sensi-Disc™ are indicated for *in vitro* agar diffusion susceptibility testing when there is a need to determine the susceptibility of bacteria to telithromycin. The concentration of telithromycin 15 µg has been shown to be active in vitro against most strains of the microorganisms listed: *Staphylococcus aureus* (methicillin and erythromycin susceptible only), *Streptococcus pneumoniae* (including multi-drug resistant isolates), *Haemophilus influenzae, Streptococcus pyogenes* (erythromycin susceptible isolates only), *Streptococci* (Lancefield groups C and G) and Viridans group streptococci.

3. Special conditions for use statement(s):

   The ability of the Telithromycin 15 µg BBL™ Sensi-Disc™ to detect resistance with Staphylococcus aureus (methicillin and erythromycin susceptible isolates only) is unknown because these strains have not yet been detected and should be retested. If the non-susceptible result is obtained the strain should be sent to a reference laboratory for further testing.

   For prescription use only.

4. Special instrument requirements:

   None

I. Device Description:

Telithromycin 15 µg BBL™ Sensi-Disc™ utilizes 6-mm disks prepared by impregnating absorbent paper with a known concentration of telithromycin. Disks are marked on both sides with letters and numbers designating the agent and the drug concentration. Sensi-Disc™ agents are furnished in cartridges containing 50 disks each.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Ciprofloxacin

2. Predicate 510(k) number(s):

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	An in vitro diagnostic product for clinical susceptibility testing of aerobic gram positive and gram negative bacteria	same
Inoculum	Prepared from colonies using the direct inoculation method or growth method	same
Inoculation method	Direct equated to a 0.5 McFarland turbidity standard	same

Difference		
Item	Device	Predicate
Antibiotic	telithromycin	ciprofloxacin

K. Standard/Guidance Document Referenced (if applicable):

CLSI/NCCLS M7 (M100-S15) "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard". The Center for Drug Evaluation and Review (CDER) pharmaceutical approved package insert, developed during clinical trial studies, was used for Interpretive Criteria and Quality Control (QC) Expected Ranges.

L. Test Principle:

BBL™ Sensi-Disc™ utilize dried filter paper disks impregnated with known concentrations of antimicrobial agents that are placed onto the test medium surface. The standard method of testing is the Kirby-Bauer method. The recommended test medium is cation-adjusted Mueller-Hinton agar supplemented with the appropriate concentration of calcium. Four to five colonies are transferred to 5 ml of a suitable broth medium. The broth is incubated at 35-37° C for 2 to 8 hours until a light to moderate turbidity develops. Alternately, a direct broth or saline suspension of colonies may be prepared from an 18-24 hour agar plate culture. The final inoculum density should be equivalent to a 0.5 McFarland turbidity standard. The inoculum density may also be standardized photometrically. Within 15 minutes of inoculum preparation, the Mueller-Hinton agar is streaked to obtain an even inoculation. Disks are aseptically placed onto the agar surface with a disc dispenser or sterile forceps to ensure contact with the test surface. Plates are

incubated in an ambient air incubator at 35-37° C. Fastidious organisms (*Haemophilus* spp., *Neisseria gonorrhoeae* and some *Streptococcus pneumoniae*) are tested using appropriate media incubated in a CO_2 enriched atmosphere, as recommended in the CLSI M7 Approved Standard document. After incubation the media is examined, and zones of inhibition around the disks are measured and compared against recognized zone size ranges for the antimicrobial agent being tested.

M. Performance Characteristics (if/when applicable):

Descriptive characteristics were sufficient for this disk, because the drug studies, evaluated by CDER at the time of telithromycin approval, generated the Interpretive Criteria and QC Expected Ranges.

1. Analytical performance:

   a. Precision/Reproducibility:

   Not applicable

   b. Linearity/assay reportable range:

   Not applicable

   c. Traceability, Stability, Expected values (controls, calibrators, or methods):

   Not applicable

   d. Detection limit:

   Not applicable

   e. Analytical specificity:

   Not applicable

   f. Assay cut-off:

   Not applicable

2. Comparison studies:

   a. Method comparison with predicate device:

   Not applicable

   b. Matrix comparison:

   Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range in millimeters:

Staphylococcus aureus >=22 (S)*
Streptococcus pneumoniae >=19 (S), 16-18 (I), <=15 (R)
Haemophilus species >=15 (S), 12-14 (I), <=11 (R)

N. Proposed Labeling:

The Interpretive Criteria, Q.C. isolates and the Expected Ranges are the same as recommended by the FDA/CDER in the approved pharmaceutical package insert. All values will be included in the device package insert. The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

*The current absence of data on Methicillin Susceptible *Staphylococcus aureus* resistant strains precludes defining any results other than "Susceptible". Strains yielding results suggestive of a "non-susceptible" category should be submitted to a reference laboratory for further testing.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.